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(56) Documents cited
GB 1263217 A EP 0275701 A2

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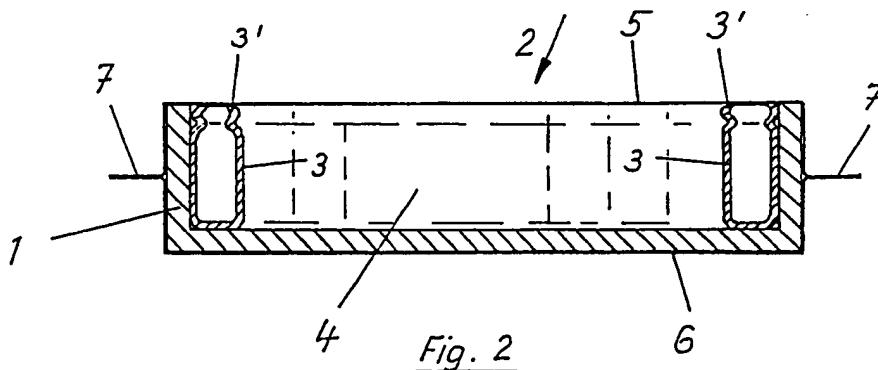
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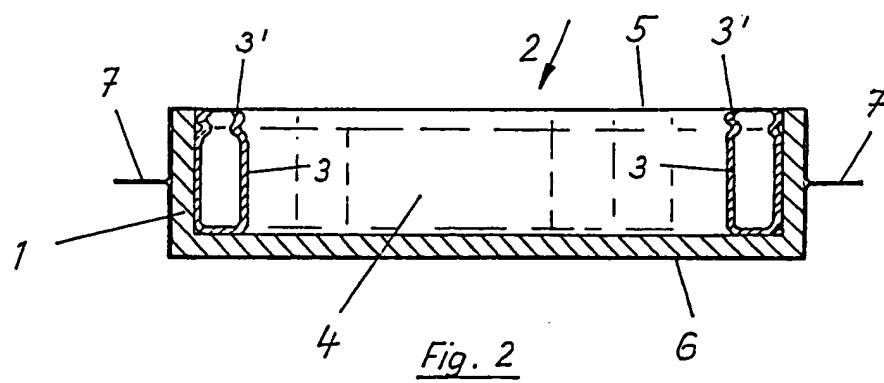
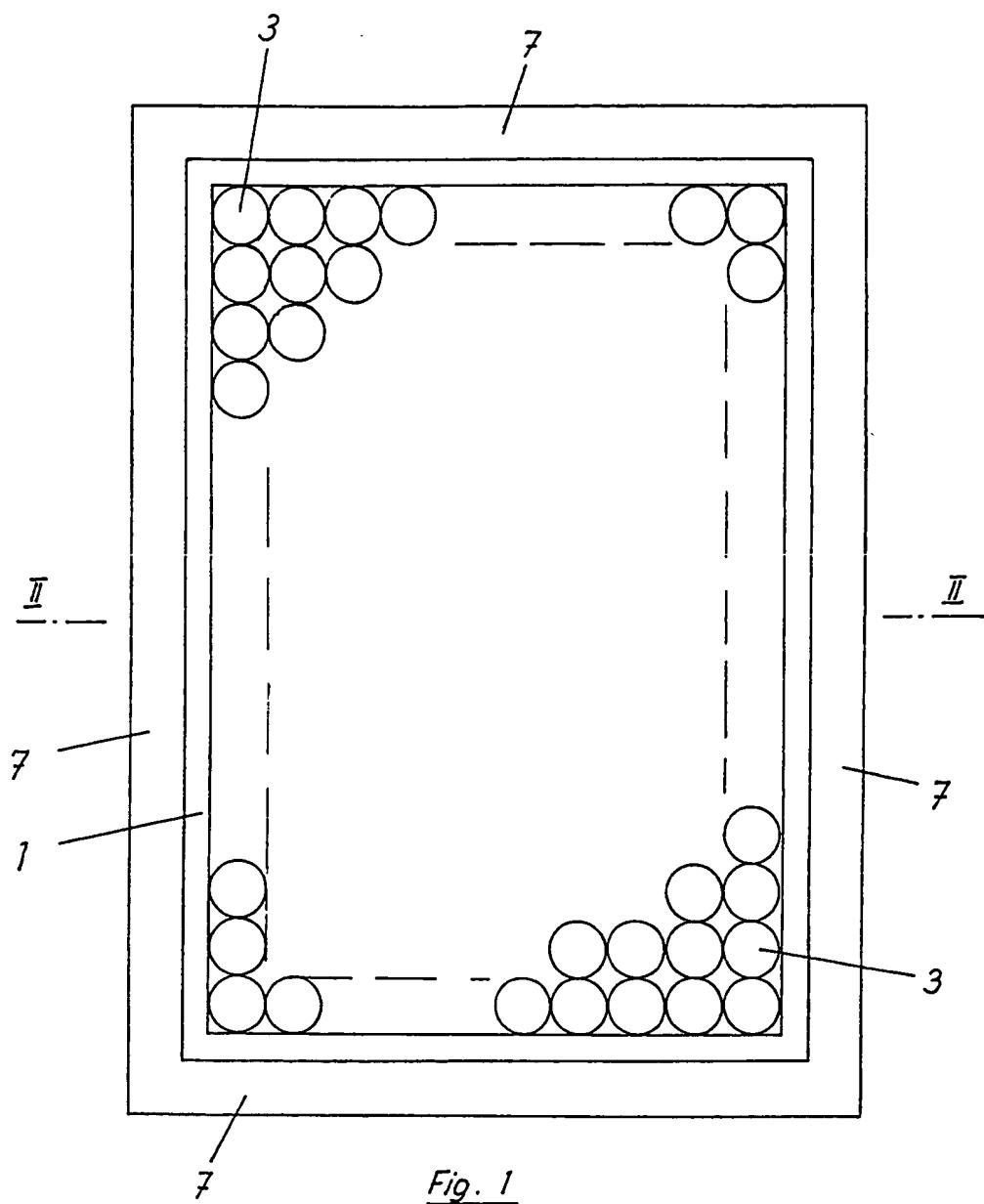
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(54) Package for sterile articles

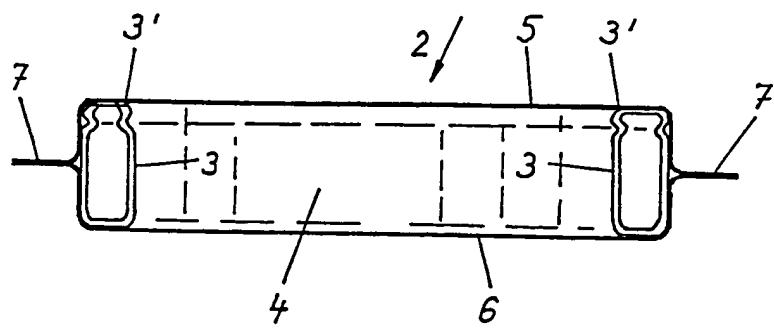
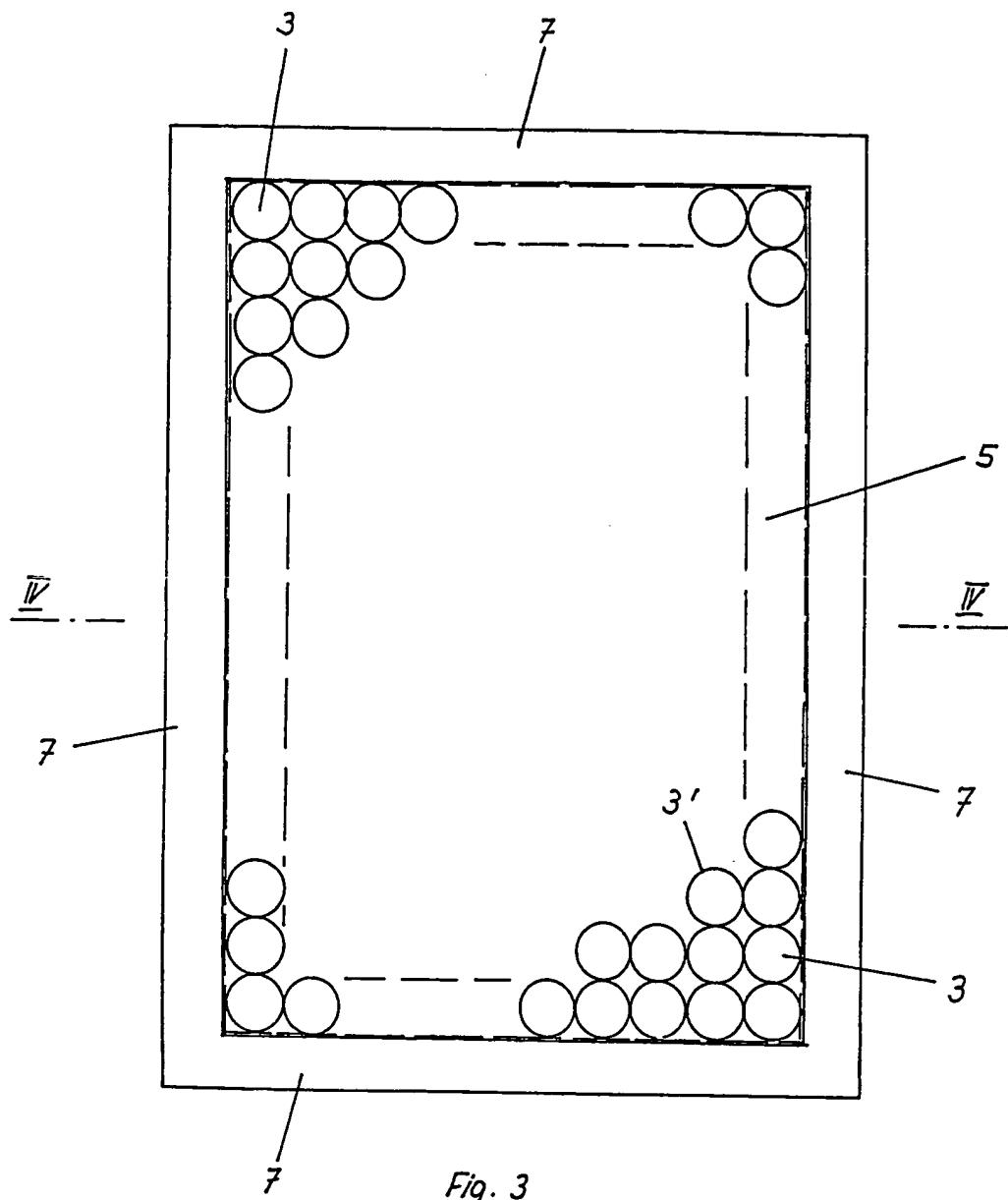
(57) A package for sterile articles (3) for pharmaceutical and/or chemical applications, comprises a plastic sheet covering (5, 6) enclosing a plurality of such articles. In order to reduce the danger of damaging the plastic sheet during transport and also to ensure that any possible damage can be obviously recognized, a vacuum is formed between the plastic sheet covering (5, 6) and the articles (3) so that the plastic sheet covering is applied closely against the articles, and a relatively strong plastic sheet (5, 6) is used. The articles (3) may optionally be supported by a tray (1) within the plastic sheet covering.



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PACKAGE FOR STERILE ARTICLES

The present invention relates to a package for sterile articles particularly but not exclusively for pharmaceutical and/or chemical applications.

In such applications there is a requirement that the articles stored in such packaging should be sterile. This applies in particular to primary packaging articles such as storage glassware, pipettes, ampoules and the like and glasses, bottles and the like which are used in pharmaceutical and/or chemical applications and which must as a rule have a certain rigidity. These objects, particularly these packaging articles, are manufactured under "clean room" conditions and are enclosed on all sides by a plastic sheet covering. They must reach a further processor, for example a pharmaceuticals manufacturer, still in this sterile condition until they arrive in the likewise sterile working area there. Experience has shown that during transport of the articles from their manufacturer to the further processor (pharmaceutical factory or the like) the plastic sheeting can be damaged, which results in biological contamination of the articles. If the damage to the packaging is not obvious, but consists only of a small tear, which may occur at a position which does not attract attention at first sight, then there is the further risk that the damage to the packaging and consequently the contamination by the further process is not noticed and the medicament in question will be poured into or will come into contact with an unsterile container.

According to one aspect of the present invention there is provided a package comprising a plurality of sterile articles and flexible sheeting surrounding the articles, the flexible sheeting having been applied to the articles under a vacuum so that it forms an air-tight enclosure in contact

with the articles, the sheeting having a thickness selected so that the package is resistant to damage in use.

The sheeting may be of plastics material and have a thickness greater than 100 μ .

An embodiment of the present invention combines the following features:

- (a) between the plastic sheet covering, on the one hand, and the articles, on the other hand, there is a vacuum, as a result of which the plastic sheeting is applied closely against the articles, and
- (b) a relatively strong plastic sheet is used.

Thus two effects may be obtained simultaneously. In the first place the risk of damaging the plastic sheet, as a rule by tearing it open, is substantially reduced by the use of a thicker plastic sheet. In addition, on account of the vacuum existing between the plastic sheeting and the articles, the sheeting is applied very tightly against the articles. A closely applied sheet of this kind may be torn substantially less easily during transport than a sheet which bears only partially against the articles to be protected and is partially slightly spaced from the articles. In the latter case those regions of the plastic sheeting which project loosely outwards or hang loosely can be relatively easily torn by, for example, a sharp edge or object or also by the hand of a transportation worker. Thus the features (a) and (b) of the combination in accordance with the invention have a synergistic effect. Also, in the case of an arrangement in accordance with the invention, should the sheet become torn by accident, the result is the release of the vacuum between the sheet and the articles located inside it. This in turn results in the sheet no longer bearing closely against the articles but instead a

layer of air is formed between them. This can be immediately and obviously recognized by the further processor of the articles in a medical products factory or the like. The risk of further processing of a contaminated article is thereby substantially reduced, first as a result of the substantially improved strength of the packaging and second, processing of a contaminated article may be reliably avoided as a result of the obvious visual indication of any damage.

Packaging according to the present invention may further comprise an open container containing the plurality of articles, the enclosure surrounding the open container in contact therewith.

The invention may also provide an arrangement for storing and/or transporting small objects for pharmaceutical and/or chemical applications, in particular primary packaging articles such as storage glassware, pipettes, ampoules and the like, wherein a tray-like or trough shaped receiving container, which is open at the top, is filled with the objects and is enclosed on all sides by a plastic sheet covering. In this connection the tasks are the same as those stated hereinabove, namely both to arrange for a reduction of the risk of damaging the plastic sheet during transport and also to ensure that any damage can be obviously recognized.

Hereby the advantages obtained are the same as those mentioned above, but in this case the sheeting bears tightly not only on the objects but equally tightly on the container.

Whereas the plastic sheets previously used had a thickness of about 40μ , in accordance with a preferred embodiment of the invention a sheet thickness in the range 150 - 200μ is used.

The enclosure may comprise a pair of flexible plastic sheets sealed together at their peripheral edges.

According to a further aspect of the present invention, there is provided a method of making a package of sterile articles, comprising surrounding a plurality of such articles with flexible sheeting, and creating a vacuum between the plurality of articles and the flexible sheeting, to form an air-tight enclosure surrounding the articles and in contact therewith.

Further details and advantages of the invention will now be described with reference to the specific embodiments shown in the drawings, in which:-

Figure 1 shows a plan view of an embodiment of the present invention,

Figure 2 shows a cross-sectional view along the line II-II in Figure 1,

Figure 3 shows a plan view of an alternative embodiment of the present invention, and

Figure 4 shows a cross-sectional view of the line IV-IV in Figure 3.

The embodiment shown in Figures 1 and 2 comprises a trough-like receiving container or tray 1, made for example of plastic, which is open at its upper face 2 so that the objects to be packed, in this case small bottles 3, can be inserted in it. It is understood that the bottles 3 fill the internal space 4 of the tray 1.

The tray filled with the objects 3 is enclosed by a plastic sheet covering, which in this case consists of two lengths 5 and 6 which are welded or stuck together in an air-tight manner at their peripheral edges 7. A vacuum is then created between the lengths 5 and 6 thus fixed together

in an air-tight manner so that the lengths 5 and 6, on account of the external air pressure, are applied tightly against the tray 1 and the upper edges 3' of the objects 3. The enveloping of the tray together with the objects inserted in it, in particular the primary packaging articles mentioned in the introduction, can be performed by known techniques such as shrink wrapping. The air-tight connection of the lengths 5 and 6 and the creation of the vacuum can also be achieved using known techniques which therefore do not need to be separately described herein.

The thickness of the lengths of plastic sheet 5 and 6 is at least about 100 μ and preferably in the range between 150 and 200 μ .

As a result of the stability of the plastic sheeting and its tight application against the tray and the objects, in particular against the primary packaging articles mentioned in the introduction, the advantages mentioned in the introduction are obtained. In this connection it should also be borne in mind that a tray packed in this way of for example 25 x 40 cm standard size and a height of about 4 cm, as a result of filling with objects which as a rule are made of glass, has a considerable weight and because of this weight can be damaged during transport if precautions not in accordance with the invention are employed.

The alternative embodiment shown in Figures 3 and 4 shows a plurality of objects to be packed together, in this case likewise small bottles 3, which are enclosed by a plastic sheet covering made from the lengths 5 and 6 which are welded or stuck together at their peripheral edges 7 in an air-tight manner. In this case too there is a vacuum between the lengths 5 and 6 thus connected together in an air-tight manner, and consequently the lengths 5 and 6 are applied tightly against the objects 3, including their upper edges 3', as a result of the external air pressure. With

regard to the enveloping of these objects and also the production of the vacuum, reference is made to the statements made above.

Thus, embodiments of the invention both reduce the risk of damaging the plastic sheeting during transport and also ensure that any possible damage can be obviously recognized.

CLAIMS:

1. A package comprising a plurality of sterile articles and a flexible sheeting surrounding the articles, the flexible sheeting having been applied to the articles under a vacuum so that it forms an air-tight enclosure in contact with the articles, the sheeting having a thickness selected so that the package is resistant to damage in use.
2. A package as claimed in claim 1, in which the sheeting is of plastics material and has a thickness greater than 100μ .
3. A package as claimed in claim 2, in which the sheeting has a thickness of between 150μ and 200μ .
4. A package as claimed in any one of claims 1 to 3, further comprising an open container containing the plurality of articles, the enclosure surrounding the open container in contact therewith.
5. A package as claimed in claim 4, in which the container comprises a flat base and side walls projecting upwardly from the periphery of the flat base.
6. A package as claimed in one of claims 1 to 5, in which the enclosure comprises a pair of flexible plastic sheets sealed together at their peripheral edges.
7. A package as claimed in claim 6 when dependent on claim 5, in which the pair of flexible plastic sheets are arranged respectively above and below the flat base and are sealed together at their peripheral edges adjacent the side walls.
8. A package substantially as herein described with reference to and as shown in Figures 1 and 2, or Figures 3 and 4 of the accompanying drawings.

9. A method of making a package of sterile articles, comprising surrounding a plurality of such articles with flexible sheeting, and creating a vacuum between the plurality of articles and the flexible sheeting, to form an air-tight enclosure surrounding the articles and in contact therewith.

10. A method as claimed in claim 9, in which the step of surrounding the plurality of articles with flexible sheeting comprises applying a pair of flexible plastic sheets to opposite sides respectively of the plurality of articles wherein the pair of flexible sheets are sealed together at their peripheral edges.

11. A method as claimed in claim 9 or 10, further comprising, before the step of surrounding the articles, placing the articles in an open container, so that the flexible sheeting forms an air-tight enclosure around the container in contact therewith.

12. A method substantially as herein described with reference to Figures 1 and 2 or Figures 3 and 4 of the accompanying drawings.

Patents Act 1977

Examiner's report to the Comptroller under
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Relevant Technical fields

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Search Examiner

S R SMITH

(ii) Int CI (Edition 5) B65D 81/20, 85/42

Date of Search

(i) UK Patent Office

18 SEPTEMBER 1992

Databases (see over)

(i) UK Patent Office

(ii) ONLINE DATABASES: WPI

Documents considered relevant following a search in respect of claims

1-12

Category (see over)	Identity of document and relevant passages	Relevant to claim(s)
X, Y	GB 1263217 (AMERICAN CYANAMID) See line 52 of page 3 to line 35 of page 4	X: 1, 2, 6, 9, 10 Y: 3, 4, 5, 7, 11
Y	EP 0275701 A2 (NALGE) See lines 3-34 of column 3 and lines 33-39 of column 4	3, 4, 5, 7, 11



Category	Identity of document and relevant passages	Relevance to claim(s)

Categories of documents

X: Document indicating lack of novelty or of inventive step.

Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.

A: Document indicating technological background and/or state of the art.

P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

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